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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,496

02/12/2004

Christopher Charles Andrews

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42074 7590 12/29/2008

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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

12/29/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-OfficeActionBSC@faegre.com

Office Action Summary	Application No. 10/777,496	Applicant(s) ANDREWS ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-9, and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/22/2008 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: wherein the side opening member is “configured to deform away from the lower edge of the lead body so as to enlarge the side opening.”

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3731

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

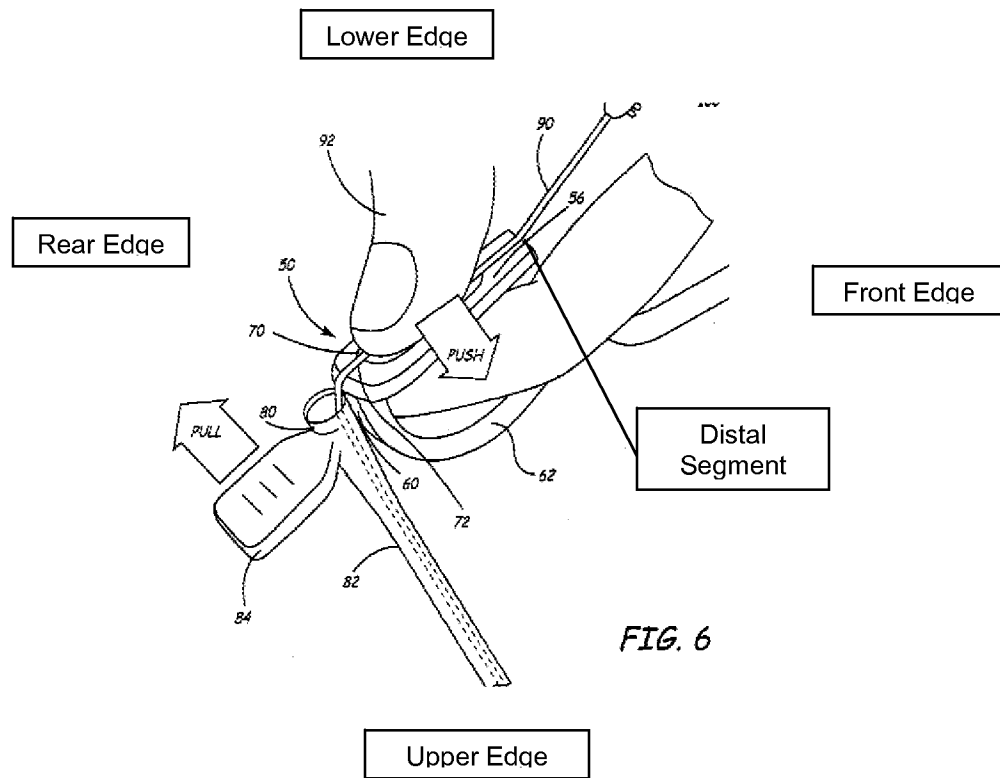
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1-3, 5-9, and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardeski et al. (US 2003/0181935 A1).

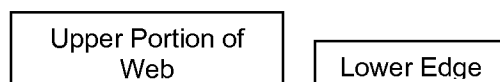
With regard to **claims 1 and 9**, Gardeski et al. (hereinafter Gardeski) discloses a device for removing a guide catheter from a linear lead (see entire document). The device comprises a body (62) having a front, rear, upper, and lower edge. The edge sides are all relative placement terms such that the upward side, as shown in the figures, can be deemed a lower edge. Furthermore, the device is configured for use in an upward down placement which would cause the lower and upper edge to be as such shown below.

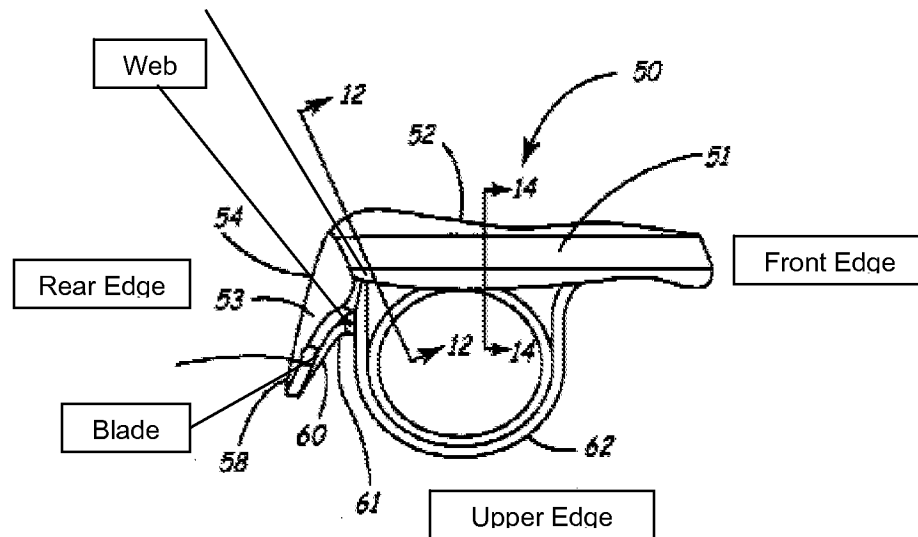
As shown in Figure 4 and below, Gardeski discloses a distal lead management segment (51) having an outer surface and comprising a side opening member, the rear or front opening ([0050]). The lumen through the side opening (72) overlaps the instantly claimed central opening since it is sized to engage the linear lead. The distal lead management segment is adjacent the lower edge and positioned between the front and rear edges of the body. Additionally, the device of Gardeski only secures the linear

lead so that it is adapted to allow the guide catheter to pass about an outer surface of the distal segment.



A blade (60) is mounted on the distal lead management segment (51) and connected to the body (62) by a connecting segment located between the lower edge and the distal segment (column 7, line 61 through column 8, line 10). As shown in Figure 3 and below, the distal lead management segment comprises a rear portion (53) that extends distal of the blade and overlaps the instantly claimed outer surface. Therefore, the blade is then mounted between the lower edge and this outer surface.



**FIG. 3**

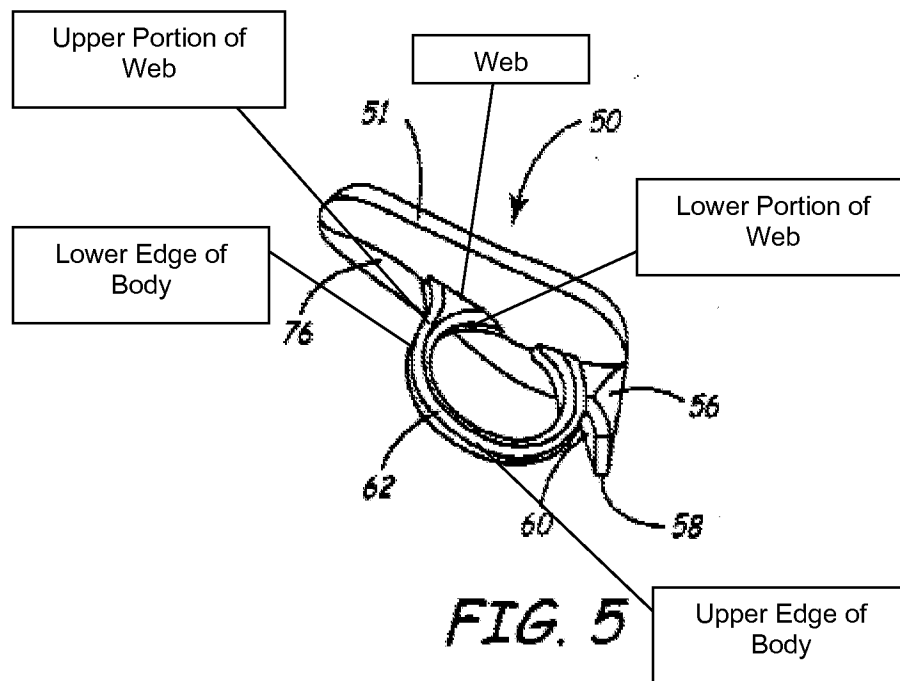
70

The blade is further disclosed as having a sawtooth configuration, which clearly overlaps the first and second cutting portions ([0045]). Further, a notch would be present between each cutting portion.

Gardeski does not specifically disclose (i) the connecting segment as a web or (ii) the side opening member configured to deform and such that the linear object can be snapped into the central opening.

With regard to (i) above, it is the examiner's position that it would have been obvious at the time of the invention to one ordinary skill in the art for the connecting segment to comprise several cavities. This would advantageously reduce the weight of the device which allows for easier manipulation. Therefore, the connecting segment of Gardeski comprising several cavities would clearly overlap the instantly claimed web.

As shown above, the web of Gardeski connects to the lower edge of the device and includes an upper portion and a lower portion. The upper portion connects to the lower edge of the body. Additionally, the distal lead management segment is connected directly to the lower portion of the web.



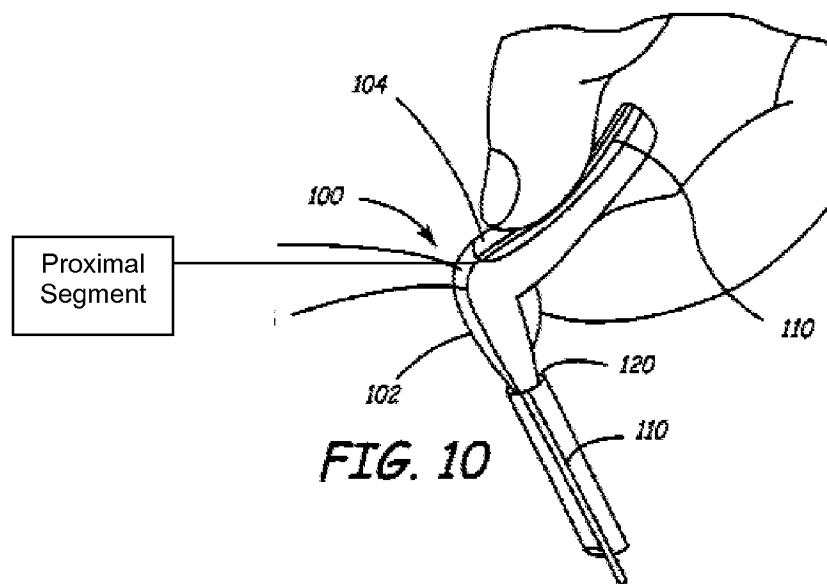
With regard to (ii) above, Gardeski teaches that the central opening (72) is sufficiently deep to receive the entire linear lead body ([0051]). Gardeski further disclose the central opening and side opening member comprised of a low durometer polymer ([0059]). Since a low durometer polymer is capable of deforming when contacted, it would have been obvious at the time of the invention for the central opening and side opening member of Gardeski to be sized accordingly so that the linear lead is snapped into the central opening causing the polymer of the side opening member to deform. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the side opening member to be initially smaller than

Art Unit: 3731

the linear lead and expand and deform when the lead is inserted into the device. This would allow for a tighter fit on the lead. When the polymer expands so that the lead is placed on the device, the side opening deforms and opens further so that the opening sides move away from the linear lead.

With regard to **claim 2**, since the cutting blade (60) is positioned close to the distal lead management segment and comprises the notch, it is the examiner's position that the notch is proximate the distal segment (Figure 3).

With regard to **claim 3**, Gardeski also discloses an arcuate side opening forming a central opening and therefore overlaps the instantly claimed proximal segment.

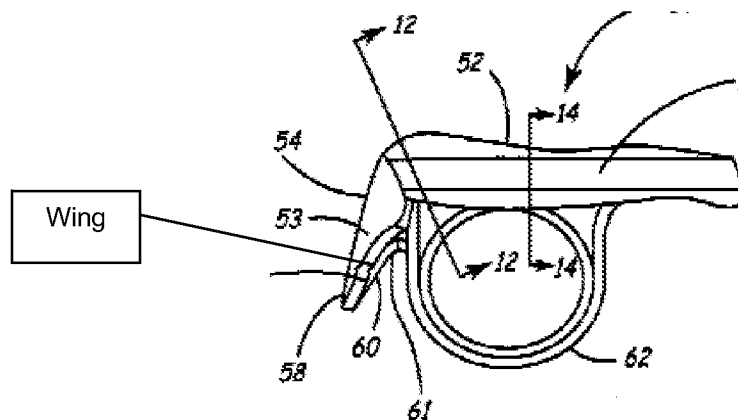


With regard to **claim 5**, Gardeski discloses a device for removing a guide catheter from a linear lead comprising a proximal and a distal segment. Gardeski further teaches wherein channel (72), which runs through the proximal and distal segments, varies in size and shape along the length of the channel. Although Gardeski does not specifically disclose wherein the distal segment has a forward smaller

Art Unit: 3731

diameter and a rearward larger diameter, since this limitation is within the scope of Gardeski, it would have been obvious to one of ordinary skill at the time of the invention for the distal segment of Gardeski to have a forward smaller diameter and a rearward larger diameter.

With regard to **claims 6 and 11**, Gardeski, discloses laterally opposing wings. One wing, as shown below, comprises the distal tip portion of nose (53) with the other wing being the equivalent on the other side of the device. Each wing is angled downward and is rearward of the blade.

**FIG. 3**

With regard to **claim 7**, it is also the examiner's position that when the distal segment comprises a forward smaller diameter and a rearward larger diameter, a transition point would be created between these two segments. As shown in Figure 3, the wings would be close to the transition point and therefore adjacent.

With regard to **claim 8**, Gardeski discloses a nose (53) extending from the distal segment and adapted to be inserted within the guide catheter (Figure 3; [0047]).

Response to Arguments

6. Applicant's arguments, filed 09/22/2008, with respect to Brenner (US 6,497,681 B1) have been fully considered and are persuasive. The rejection has been withdrawn since Brenner does not disclose a side opening member having a first dimension smaller than a diameter of the linear lead such that the side opening member is configured to deform so that the linear lead can be snapped into the central opening.

7. Applicant's arguments filed 09/22/2008 have been fully considered but they are not persuasive. Applicants argue that the side opening and central opening of Gardeski is not capable of retaining the lead without a user applying pressure. However, the instant claims do not limit the device such that a user's input is restricted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 3731

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/15/2008

/Amy T Lang/

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731